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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,253	01/18/2002	Robert L. Stout	32265	7968

7590 08/25/2006

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,253	STOUT, ROBERT L.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,7-25 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 4, 7-25 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to communication filed 6/30/2006. Of note, this application has been transferred to another examiner. Please direct all correspondences regarding this application to Examiner Michelle Horning of Art Unit 1648.

The status of the claims is as follows: claims 1, 2, 5, 6, 26-30 have been cancelled and claims 3, 4, 7-25 and 31 are under current examination.

The following rejections from the previous office action are withdrawn in view of Applicant's arguments and amendments:

1. 35 USC 112, 2;

2. 35 USC 102; and

3. 35 USC 103.

Briefly, the rejection made under 35 USC 112, 2 is withdrawn due to the claim amendments filed 6/30/2006. Both rejections made under 35 USC 102 and 35 USC 103 are withdrawn because, as noted by the Applicant's arguments, the prior art reference used for these rejections is not drawn to a multiple-antigen array.

Claim Objection

Claim 12 is objected to because of the following informalities: assay is misspelled. Appropriate correction is required.

Claim Rejections

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4, 7-25 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 5,683,864 (Houghton et al), and further in view of Teo et al (1992) and Lazizi et al (1992). The limitations of the claims above are:

1. obtaining a sample from an individual;

2. performing a multiple HCV antigen array;

3. determining the optical density of the sample; and

4. determining whether the sample contains an OD that correlates to chronic HCV.

Houghton et al teach an immunoassay for anti-HCV antibodies in which a combination of antigens is used (entire document). Samples used for this assay include the serum of individuals (see example 7). Table 1 (starting on col. 7) reveals the plurality of antigens found in this assay. Thus, limitations 1 and 2 above are met. Houghton el al do not teach a method of quanitification, more specifically, determining the optical density of the sample and an OD value that correlates to chronic HCV infection.

The method of optical density is widely used in the art to determine the concentration of proteins in a given sample. Teo et al is one of *many* prior art references that determine the OD values displayed by HCV immunoassays. Teo et al disclose a method in which a commercial enzyme inmmunoassay (EIA) is used to screen for antibodies to hepatitis C virus. Within this EIA, both c200 and c22 antigens are used (see methods). Teo at al teach that "high OD readings" are equated to HCV antibody positive (see conclusions). Lazizi et al also teach the use of a multiple antigen array combined with optical density measurements (see Materials and Methods). Further, Lazizi et al, as well as many other references, teach that "In chronically HCV-infected patients, high levels of anti-HCV antibodies are often associated with the presence of HCV RNA sequences in sera" (see discussion). Thus, this correlation is already well known in the prior art.

Given that all of the four limitations above are common and well known in the prior art, it would have been obvious to one of ordinary skill in the art to combine the methods taught by Houghton et al, Teo et al and Lazizi et al. in order to quantify antibody-antigen complexes in an assay to determine whether an individual is chronically infected by HCV. One would have been motivated to do so, as suggested by Teo et al (see Abstract, Aim), to devise a scheme in which results validated by enzyme immunoassay (EIA) would not require costly and methodically elaborate supplemental assays. There would have been reasonable expectation of success, given that all of the techniques including limitations 1-4 are well known and widely used. Thus,

the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see htt://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michelle Horning
Patent Examiner

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